DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 19, 2014

MAQUET Cardiopulmonary AG
Sarah Betz
Manager Regulatory Affairs
Kehler Strasse 31
76437 Rastatt, Germany

Re: K140569
Trade/Device Name: Antegrade cardioplegia cannula (n-type)
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: October 17, 2014
Received: October 22, 2014

Dear Sarah Betz,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: To be assigned K140569

Device Name: Antegrade Cardioplegia Cannula (N-Type)

Intended Use:
The Antegrade Cardioplegia Cannula acts as an infusion cannula for cardioplegic solutions. The cardioplegic solution is perfused via the aortic root into the coronaries. Furthermore, the Antegrade Cardioplegia Cannula can be used for left ventricular relaxation and aortic arch de-airing during cardiopulmonary bypass. The maximum duration of use is 6 hours.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Device Proprietary Name: Antegrade Cardioplegia Cannula (N-Type)

Common Name: Cardiopulmonary bypass vascular catheter, cannula or tubing

Classification Regulation: 870.4210

Device Class: II

Submitter's Name: MAQUET Cardiopulmonary AG
Address: Kehler Straβe 31
76437 Rastatt, Germany
Contact Person: Sarah Betz
Telephone Number: +49 7471 9973 440
Fax Number: +49 7471 9973 8667

Date Summary Prepared: February 22, 2014

Device Description

The Antegrade Cardioplegia Cannula (N-Type) by MAQUET is used to administer cardioplegia solution into the heart in operative procedures where cardiopulmonary bypass is utilized. The cardioplegia solution causes asystole so that the operative procedure can be performed on a still heart.

The Antegrade Cardioplegia Cannula (N-Type) is inserted into the aortic root through a purse-string suture towards the aortic cross clamp. This method allows the cardioplegia solution to flow into the coronary arteries, which is known as antegrade delivery.

Purpose of Submission

The Antegrade Cardioplegia Cannula (N-Type) is a redesign of the currently marketed Antegrade Cardioplegia Cannula, cleared under K020515. The main reason for designing the new cannula is to replace the plasticizer DEHP in blood contacting components containing PVC as the raw material. In addition, two new configurations of

the Antegrade Cardioplegia Cannula (N-Type) are being added, the Cannula with Trocar and Pressure Monitoring System and the Cannula without a Trocar. Special configurations are being added, such as an additional clamp on the infusion line and different length of infusion line.

Intended Use:
The Antegrade Cardioplegia Cannula acts as an infusion cannula for cardioplegic solutions. The cardioplegic solution is perfused via the aortic root into the coronaries. Furthermore, the Antegrade Cardioplegia Cannula can be used for left ventricular relaxation and aortic arch de-airing during cardiopulmonary bypass. The maximum duration of use is 6 hours.

Predicate Device:
The predicate device is the Jostra Antegrade Cardioplegia Cannula, manufactured by MAQUET Cardiopulmonary AG, which was cleared on April 24, 2002 under K020515.

Technological Characteristics/Substantial Equivalence:
The Antegrade Cardioplegia Cannula (N-Type) has the same intended use, is manufactured from the same or similar materials and incorporates the same technological characteristics as the predicate device.

The Antegrade Cardioplegia Cannula (N-Type) is provided sterile by ethylene oxide and is for single use only.

Performance Data:
The Antegrade Cardioplegia Cannula (N-Type) has been evaluated through non-clinical performance testing for flow rate, pressure resistance, leak testing, bond joint tensile strength, kink resistance, stress cracking of the handle, functional testing of the air plug and vent plug as well as the clamp and corrosion of the trocar. The Antegrade Cardioplegia Cannula (N-Type) met all of the acceptance criteria.

Biocompatibility testing was also performed and included Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Hemocompatibility and Genotoxicity. The Antegrade Cardioplegia Cannula (N-Type) passed all biocompatibility testing.

The Antegrade Cardioplegia Cannula (N-Type) was found to be substantially equivalent to the predicate device based on non-clinical testing.